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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,736

Applicant(s)

FALLON ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 16 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-16 and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 13 and 32 have been amended, claim 14 has been cancelled and claim 39 has been added as requested in the amendment filed on January 21, 2005. Following the amendment, claims 13, 15-16 and 32-39 are pending in the instant application.
2. Newly submitted claim 39 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 39 is directed to a method classified in class 435, subclass 7.71, for example, which recites different steps, such as a step of assaying activity of MuSK, and achieves a different goal, therefore constituting an invention patentably distinct from the originally elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 13, 15-16 and 32-38 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on January 21, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

6. Claims 13, 15-16 and 32-38, as amended, stand rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270 for reasons of record in section 10 of Paper mailed on September 20, 2004.

Applicant traverses the rejection on the premises “that Ruoslahti et al. teaches only the possible use of biglycan for reducing scar formation, and the administration of decorin in an animal model by creating a wound by cutting down to the muscle and then applying decorin. [...] There is no teaching that cutting down to the muscle would be an appropriate method for administration in a human as recited in amended claim 13” (second paragraph at page 8 of the Response). Applicant further refers to *In re Robertson* and *Ex parte Levy* to argue that inherency may not be established by probability and must flow from the teachings of the prior art. Applicant’s arguments have been fully considered but are not deemed to be persuasive for the reasons that follow.

To satisfy 35 U.S.C. 102(b) requirements, the prior art reference must fully describe the claimed invention. The patent of Ruoslahti et al. expressly describes administration of biglycan to a wound as a method for prevention or reduction of scarring (see column 3, Summary of the Invention, for example). Applicant is advised that the patent is not limited to the working examples described therein, and, therefore, Applicant’s argument regarding administration of biglycan to an animal in working examples of Ruoslahti et al. document *versus* administration of biglycan to a human subject, as currently claimed in the instant application, is not persuasive. To constitute a proper prior art disclosure, a patent does not have to provide working examples of every specific embodiment, and, if this were the case, Applicant’s own specification would

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suffer from substantial deficiencies. Ruoslahti et al. document clearly describes a method of wound treatment and uses a mouse animal model to support the claimed invention, and, therefore, one readily appreciates that the disclosure of Ruoslahti et al. is not limited to treatment of wounds and reduction of scarring in mice only.

At top of page 9 of the Response, Applicant argues that “Ruoslahti et al. do not suggest any mode of administration in a human other than by treatment of a wound. Given that such treatment was not attempted in humans, it is not inevitable that any such treatment would result in adequate dosing to the muscle to achieve the claimed effect”. However, the instant invention, as currently claimed, is not limited to any particular method or mode administration of biglycan. Claims 13, 15-16 and 32-38, as written, encompass a method for activating a postsynaptic membrane of a cell by contacting the cell with biglycan, and Ruoslahti et al. patent teaches such contact. Thus, absent evidence to the contrary, postsynaptic membranes of muscle cells were activated upon contact with biglycan as disclosed in Ruoslahti et al. document. As fully explained in the previous office action of record, the result of the same procedure is reasonably expected to be same. In order to qualify as an anticipatory reference, the disclosure need not be express. Even failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation: In *Atlas Powder Co. v. IRECO, Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999).

Therefore, for reasons fully explained in previous office communications of record and reasons above, the instant rejection is maintained.

Conclusion

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7. No claim is allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December

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28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

April 01, 2005